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AMENDMENTS TO THE CLAIMS

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146. (currently amended) A pharmaceutical formulation, comprising: (a) fenofibrate having a first fraction and a second fraction, wherein the first fraction is comprised of a plurality of solid particles; and (b) a pharmaceutically acceptable vehicle comprising at least one compound selected from the group consisting of a hydrophilic surfactant, a lipophilic surfactant, a triglyceride and a solubilizer, wherein said formulation is encapsulated in an exterior capsule such that the first fraction and the second fraction are segregated. the first fraction of the fenofibrate is suspended in the vehicle and the second fraction of the fenofibrate is solubilized in the vehicle, said first fraction representing about 5 wt. % to about 80 wt. % of the total fenofibrate and said second fraction representing about 20 wt. % to about 95 wt. % of the total fenofibrate.

147. (currently amended) The pharmaceutical formulation of claim 146, further including an additional active agent.

148. (previously presented) The pharmaceutical formulation of claim 146, wherein the first fraction represents about 5 wt. % to about 80 wt. % of the fenofibrate, and the second fraction represents about 20 wt. % to about 95 wt. % of the fenofibrate.

149. (previously presented) The pharmaceutical formulation of claim 148, wherein the first fraction represents about 30 wt. % to about 80 wt. % of the fenofibrate, and the second fraction represents about 20 wt. % to about 70 wt. % of the fenofibrate.

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150. (previously presented) The pharmaceutical formulation of claim 149, wherein the first fraction represents about 50 wt. % to about 70 wt. % of the fenofibrate, and the second fraction represents about 30 wt. % to about 50 wt. % of the fenofibrate.

151. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles are comprised of powder, granules, pellets, beads, or combinations thereof.

152. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles are associated with each other to form at least one dosage unit comprised of a granule, pellet, bead or tablet suspended in the vehicle.

153. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles are contained within at least one capsule suspended in the vehicle.

154. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles are prepared by a process selected from melt extrusion, nanoencapsulation, lyophilization, spheronization, coacervation, cryopelletization, crystallization, antisolvent precipitation, precipitation from expanded supercritical fluid, spray drying, spray coating, spray congealing, and combinations thereof.

155. (previously presented) The pharmaceutical formulation of claim 154, wherein the solid particles are subjected to further processing after preparation thereof.

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156. (previously presented) The pharmaceutical formulation of claim 155, wherein the further processing comprises size reduction.

157. (previously presented) The pharmaceutical formulation of claim 156, wherein the size reduction is carried out by a process selected from grinding, milling, micronization, nanosizing, and combination thereof.

158. (previously presented) The pharmaceutical formulation of claim 157, wherein the solid particles have a mean diameter in the range of about 0.1 μm to about 100 μm .

159. (previously presented) The pharmaceutical formulation of claim 156, wherein the size reduction is carried out in the presence of a surfactant, a hydrophilic polymer, a lipid, a gelatin, a saccharide, or a mixture thereof.

160. (previously presented) The pharmaceutical formulation of claim 156, wherein the size reduction is carried out in the presence of the vehicle.

161. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles contain at least one pharmaceutically acceptable excipient.

162. (previously presented) The pharmaceutical formulation of claim 146, further comprising at least one pharmaceutically acceptable additive selected from the group

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consisting of a stabilizing agent, an antioxidant, a bufferant, an antifoaming agent, a detackifier, a preservative, a chelating agent, a viscomodulator, a tonicifier, a flavorant, a colorant, an odorant, an opacifier, a binder, a filler, a plasticizer, a taste-masking agent, a lubricant, and an enzyme inhibitor.

163. (previously presented) The pharmaceutical formulation of claim 162, wherein said at least one pharmaceutically acceptable additive is a stabilizing agent.

164. (previously presented) The pharmaceutical formulation of claim 163, wherein the stabilizing agent is a suspending agent.

165. (previously presented) The pharmaceutical formulation of claim 164, wherein the suspending agent is selected from the group consisting of microcrystalline cellulose, sodium carboxymethylcellulose, powdered cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, ethylcellulose, ethyl methylcellulose, ethyl hydroxyethylcellulose, attapulgate, bentonite, hectorite, montmorillonite, silica gel, fumed silicon dioxide, colloidal silicon dioxide, acacia, agar, carrageenan, guar gum, locust bean gum, pectin, sodium alginate, propylene glycol alginate, tamarind gum, xanthan gum, carbomers, polyvinyl pyrrolidone, starch, sodium starch glycolate, tragacanth, magnesium aluminum silicate, aluminum silicate, magnesium silicate, gelatin, and glycyrrhizin.

166. (previously presented) The pharmaceutical formulation of claim 146, wherein the

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solid particles comprise at least one amorphous phase, at least one crystalline phase, or a mixture of at least one amorphous phase and at least one crystalline phase.

167. (previously presented) The pharmaceutical formulation of claim 146, wherein the solid particles further include a stabilizing agent.

168. (previously presented) The pharmaceutical formulation of claim 167, wherein said stabilizing agent is selected from the group consisting of synthetic hydrophilic polymers, surfactants, saccharides, gelatin, and combinations thereof.

169. (previously presented) The pharmaceutical formulation of claim 168, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyalkylene oxides, polyalkylene oxide-substituted C₂-C₆ diols and triols, polyalkylene oxide-substituted saccharides, poly(N-vinyl lactams), and polymers of carboxyvinyl monomers.

170. (previously presented) The pharmaceutical formulation of claim 169, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyethylene glycol, mono-poly(oxyethylene)-substituted propylene glycol, di-(polyoxyethylene)-substituted propylene glycol, mono-poly(oxyethylene)-substituted glycerol, di-(polyoxyethylene)-substituted glycerol, tri-(polyoxyethylene)-substituted glycerol, polyoxyethylated sorbitol, polyoxyethylated glucose, polyvinyl pyrrolidone, poly(N-vinyl caprolactam), and polymers and copolymers of acrylic acid, methacrylic acid and/or esters thereof.

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171. (previously presented) The pharmaceutical formulation of claim 168, wherein the saccharides are cellulosic polymers.

172. (previously presented) The pharmaceutical formulation of claim 171, wherein the stabilizing agent is hydroxypropyl methylcellulose.

173. (previously presented) The pharmaceutical formulation of claim 146, wherein the vehicle is substantially free of water-indispersible wax materials.

174. (previously presented) The pharmaceutical formulation of claim 173, wherein the water-indispersible wax materials are selected from the group consisting of beeswax, paraffin, yellow wax, hydrogenated oils, hydrogenated vegetable oil, hydrogenated soybean oil flakes and mixtures thereof.

175. (previously presented) The pharmaceutical formulation of claim 146, wherein the vehicle contains less than about 20 wt. % water.

176. (previously presented) The pharmaceutical formulation of claim 146, wherein the vehicle contains less than about 10 wt. % water.

177. (previously presented) The pharmaceutical formulation of claim 146, wherein the vehicle comprises (a) at least one hydrophilic surfactant, (b) at least one lipophilic

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surfactant, or (c) at least one hydrophilic surfactant and at least one lipophilic surfactant.

178. (previously presented) The pharmaceutical formulation of claim 177, wherein the vehicle comprises at least one hydrophilic surfactant and at least one lipophilic surfactant.

179. (previously presented) The pharmaceutical formulation of claim 146, wherein the vehicle comprises a triglyceride, a solubilizer, or a mixture thereof.

180. (previously presented) The pharmaceutical formulation of claim 146, wherein said at least one compound represents about 1 wt. % to about 99 wt. % of the formulation.

181. (previously presented) The pharmaceutical formulation of claim 180, wherein said at least one compound represents about 10 wt. % to about 90 wt. % of the formulation.

182. (previously presented) The pharmaceutical formulation of claim 181, wherein said at least one compound represents about 20 wt. % to about 80 wt. % of the formulation.

183. (previously presented) The pharmaceutical formulation of claim 146, wherein either the first fraction of the fenofibrate, the second fraction of the fenofibrate, or both the first and second fractions of the fenofibrate are formulated for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, or targeted delayed release of the fenofibrate.

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184. (previously presented) The pharmaceutical formulation of claim 183, wherein the first fraction of the fenofibrate and the second fraction of the fenofibrate have different release profiles.

185. (previously presented) The pharmaceutical formulation of claim 183, wherein the first fraction of the fenofibrate further comprises a means for controlling release of the fenofibrate from the suspended particles.

186. (previously presented) The pharmaceutical formulation of claim 185, wherein the second fraction of the fenofibrate comprises an immediate release composition.

187. (previously presented) The pharmaceutical formulation of claim 186, wherein the second fraction of the fenofibrate exhibits an immediate release profile.

188. (previously presented) The pharmaceutical formulation of claim 186, wherein the second fraction provides for release of at least 50% of the fenofibrate contained therein within 30 minutes at 37°C as evaluated using standard USP dissolution test equipment.

189. (previously presented) The pharmaceutical formulation of claim 188, wherein the second fraction provides for release of at least 75% of the fenofibrate contained therein within 30 minutes at 37°C as evaluated using standard USP dissolution test equipment.

190. (previously presented) The pharmaceutical formulation of claim 189, wherein the

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second fraction provides for release of at least 90% of the fenofibrate contained therein within 30 minutes at 37°C. as evaluated using standard USP dissolution test equipment.

191. (previously presented) A dosage form comprising the pharmaceutical formulation of claim 146.

192. (previously presented) The dosage form of claim 191, comprised of a capsule, preconcentrate, drop, or drink.

193. (currently amended) A pharmaceutical system for administration of an fenofibrate, comprising: (a) fenofibrate; and (b) a pharmaceutically acceptable vehicle comprising at least one compound selected from the group consisting of a hydrophilic surfactant, a lipophilic surfactant, a triglyceride and a solubilizer, wherein the relative amounts of the fenofibrate and the vehicle are such that upon admixture thereof, a first fraction of the fenofibrate is suspended in the vehicle, and a second fraction of the fenofibrate is solubilized in the vehicle, wherein said first and second fractions of are encapsulated in an exterior capsule such that the first fraction and the second fraction are segregated, and wherein the second fraction represents about 20 wt. % to about 95 wt. % of the total fenofibrate in the formulation.

194. (previously presented) The pharmaceutical system of claim 193, wherein the first fraction represents about 10 wt. % to about 80 wt. % of the fenofibrate, and the second fraction represents about 20 wt. % to about 90 wt. % of the fenofibrate.

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195. (previously presented) The pharmaceutical system of claim 194, wherein the first fraction represents about 30 wt. % to about 80 wt. % of the fenofibrate, and the second fraction represents about 20 wt. % to about 70 wt. % of the fenofibrate.

196. (previously presented) The pharmaceutical system of claim 195, wherein the first fraction represents about 50 wt. % to about 70 wt. % of the fenofibrate, and the second fraction represents about 30 wt. % to about 50 wt. % of the fenofibrate.

197. (previously presented) The pharmaceutical system of claim 196, wherein the solid particles are comprised of powder, granules, pellets, beads, or combinations thereof.

198. (previously presented) The pharmaceutical system of claim 193, wherein the solid particles are associated with each other to form at least one dosage unit comprised of a granule, pellet, bead or tablet.

199. (previously presented) The pharmaceutical system of claim 198, wherein the solid particles are contained within a capsule.

200. (previously presented) The pharmaceutical system of claim 198, wherein the solid particles are prepared by a process selected from melt extrusion, nanoencapsulation, lyophilization, spheronization, coacervation, cryopelletization, crystallization, antisolvent precipitation, precipitation from expanded supercritical fluid, spray drying, spray coating,

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spray congealing, and combinations thereof.

201. (previously presented) The pharmaceutical system of claim 200, wherein the solid particles are subjected to further processing after preparation thereof.

202. (previously presented) The pharmaceutical system of claim 201, wherein the further processing comprises size reduction.

203. (previously presented) The pharmaceutical system of claim 202, wherein the size reduction is carried out by a process selected from grinding, milling, micronization, nanosizing, and combination thereof.

204. (previously presented) The pharmaceutical system of claim 203, wherein the solid particles have a mean diameter in the range of about 0.1 μm to about 100 μm .

205. (previously presented) The pharmaceutical system of claim 202, wherein the size reduction is carried out in the presence of a surfactant, a hydrophilic polymer, a lipid, a gelatin, a saccharide, or a mixture thereof.

206. (previously presented) The pharmaceutical system of claim 202, wherein the size reduction is carried out in the presence of the vehicle.

207. (previously presented) The pharmaceutical system of claim 193, wherein the solid

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particles contain at least one pharmaceutically acceptable excipient.

208. (previously presented) The pharmaceutical system of claim 193, wherein the vehicle further comprises at least one pharmaceutically acceptable additive selected from the group consisting of a stabilizing agent, an antioxidant, a bufferant, an antifoaming agent, a detackifier, a preservative, a chelating agent, a viscomodulator, a tonicifier, a flavorant, a colorant, an odorant, an opacifier, a binder, a filler, a plasticizer, a taste-masking agent, a lubricant, and an enzyme inhibitor.

209. (previously presented) The pharmaceutical system of claim 208, wherein said at least one pharmaceutically acceptable additive is a stabilizing agent.

210. (previously presented) The pharmaceutical system of claim 209, wherein the stabilizing agent is a suspending agent.

211. (previously presented) The pharmaceutical system of claim 210, wherein the suspending agent is selected from the group consisting of microcrystalline cellulose, sodium carboxymethylcellulose, powdered cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, ethylcellulose, ethyl methylcellulose, ethyl hydroxyethylcellulose, attapulgit, bentonite, hectorite, montmorillonite, silica gel, fumed silicon dioxide, colloidal silicon dioxide, acacia, agar, carrageenan, guar gum, locust bean gum, pectin, sodium alginate, propylene glycol alginate, tamarind gum, xanthan gum, carbomers, polyvinyl pyrrolidone, starch, sodium starch glycolate,

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tragacanth, magnesium aluminum silicate, aluminum silicate, magnesium silicate, gelatin, and glycyrrhizin.

212. (previously presented) The pharmaceutical system of claim 193, wherein the solid particles comprise at least one amorphous phase, at least one crystalline phase, or a mixture of at least one amorphous phase and at least one crystalline phase.

213. (previously presented) The pharmaceutical system of claim 212, wherein the solid particles further include a stabilizing agent.

214. (previously presented) The pharmaceutical system of claim 213, wherein said stabilizing agent is selected from the group consisting of synthetic hydrophilic polymers, surfactants, saccharides, gelatin, and combinations thereof.

215. (previously presented) The pharmaceutical system of claim 214, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyalkylene oxides, polyalkylene oxide-substituted C₂-C₆ diols and triols, polyalkylene oxide-substituted saccharides, poly(N-vinyl lactams), and polymers of carboxyvinyl monomers.

216. (previously presented) The pharmaceutical system of claim 215, wherein the synthetic hydrophilic polymers are selected from the group consisting of polyethylene glycol, mono-poly(oxyethylene)-substituted propylene glycol, di-(polyoxyethylene)-substituted propylene glycol, mono-poly(oxyethylene)-substituted glycerol, di-

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(polyoxyethylene)-substituted glycerol, tri-(polyoxyethylene)-substituted glycerol, polyoxyethylated sorbitol, polyoxyethylated glucose, polyvinyl pyrrolidone, poly(N-vinyl caprolactam), and polymers and copolymers of acrylic acid, methacrylic acid and/or esters thereof.

217. (previously presented) The pharmaceutical system of claim 216, wherein the saccharides are cellulosic polymers.

218. (previously presented) The pharmaceutical system of claim 217, wherein the stabilizing agent is hydroxypropyl methylcellulose.

219. (previously presented) The pharmaceutical system of claim 193, wherein the vehicle is substantially free of water-indispersible wax materials.

220. (previously presented) The pharmaceutical system of claim 219, wherein the water-indispersible wax materials are selected from the group consisting of beeswax, paraffin, yellow wax, hydrogenated oils, hydrogenated vegetable oil, hydrogenated soybean oil flakes and mixtures thereof.

221. (previously presented) The pharmaceutical system of claim 193, wherein the vehicle contains less than about 20 wt. % water.

222. (previously presented) The pharmaceutical system of claim 221, wherein the

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vehicle contains less than about 10 wt. % water.

223. (previously presented) The pharmaceutical system of claim 193, wherein the vehicle comprises (a) at least one hydrophilic surfactant, (b) at least one lipophilic surfactant, or (c) at least one hydrophilic surfactant and at least one lipophilic surfactant.

224. (previously presented) The pharmaceutical system of claim 223, wherein the vehicle comprises at least one hydrophilic surfactant and at least one lipophilic surfactant.

225. (previously presented) The pharmaceutical system of claim 193, wherein the vehicle comprises a triglyceride, a solubilizer, or a mixture thereof.

226. (previously presented) The pharmaceutical system of claim 193, wherein either the first fraction of the fenofibrate, the second fraction of the fenofibrate, or both the first and second fractions of the fenofibrate are formulated for immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, or targeted delayed release of the fenofibrate.

227. (previously presented) The pharmaceutical system of claim 226, wherein the first fraction of the agent and the second fraction of the fenofibrate have different release profiles.

228. (previously presented) The pharmaceutical system of claim 226, wherein the first

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fraction of the fenofibrate further comprises a means for controlling release of the fenofibrate from the suspended particles.

229. (previously presented) The pharmaceutical system of claim 228, wherein the second fraction of the fenofibrate comprises an immediate release composition.

230. (previously presented) The pharmaceutical system of claim 228, wherein the second fraction of the fenofibrate exhibits an immediate release profile .

231. (previously presented) The pharmaceutical system of claim 230, wherein the second fraction provides for release of at least 50% of the fenofibrate contained therein within 30 minutes at 37°C as evaluated using standard USP dissolution test equipment.

232. (previously presented) The pharmaceutical system of claim 231, wherein the second fraction provides for release of at least 75% of the fenofibrate contained therein within 30 minutes at 37°C as evaluated using standard USP dissolution test equipment.

233. (previously presented) The pharmaceutical system of claim 232, wherein the second fraction provides for release of at least 90% of the fenofibrate contained therein within 30 minutes at 37°C as evaluated using standard USP dissolution test equipment.